CHAPTER 1

PROGRAM BACKGROUND AND RESPONSIBILITIES

Crosswalk of Regional Office Manual Exhibits

Showing Previous Location

LIST OF EXHIBITS - ROM

EXHIBIT ROM----SOM			Remarks:
4-1 I	Deleted	Regional Office Request for Additional information, HCFA-166	*Dupl. of SOM-15
4-5	156	Provider Tie-In Notice, HCFA-2007	
4-7	Deleted	Request for Validation of Accreditation Survey, HCFA-2802	Dupl. of SOM-33
4-10	Deleted	Accreditation Hospital Allegation(s) Report HCFA-2878	Obsolete
4-11	184	Advertising Order, SF-1143, and Public Voucher for Advertising, SF-1144	
4-13A	Deleted	SAEP Score Distribution	Obsolete
4-13B	Deleted	SAEP Criteria and Standards	Obsolete
4-14	Deleted	Model Letter Transmitting SAEP Review Reports to SA	Obsolete
4-17	Deleted	Monitoring Survey Summary	Obsolete
4-20	164	RO Adjudication of SA Certification Actions--Checklist and Summary Sheet	
4-21	165	Notice to a Provider that Agreement was Accepted	
4-23	166	Notice of Approval of Supplier of Services	
4-24	Deleted	Notification of Acceptance of SNF Agreement (Supplement to Agreement when SNF is in Full Compliance with All Standards	Obsolete
4-25	Deleted	Notification of Acceptance of SNF Agreement (Supplement to Agreement when Deficiencies Are to be Corrected per HCFA-2567)	Obsolete
4-26	188	Notification--Voluntary Termination of Provider Agreement Approved	
4-27	189	Notification--Approval of Voluntary Termination of a Supplier	
4-28	Deleted	Notification of Approval of Voluntary Termination (One or More Specialties) by Independent Laboratory)	Obsolete
4-30	190	Notification to Provider That Has Ceased or Is Ceasing Operation	
4-31	191	Notification to Supplier That Has Ceased or is Ceasing Operation	

* Dupl. = Duplication

LIST OF EXHIBITS - ROM

EXHIBIT ROM----SOM			Remarks:
4-35	215	Notification to Provider/Supplier Warning of Possible Termination--Failure to Disclose Financial Interest and Ownership Information	
4-36	187	Notification to Previously-Approved Supplier Of a Pending Termination	
4-38	181	Notice to Hospital Provider of Involuntary Termination	
4-41	182	Notice of Termination to Supplier	
4-42	Deleted	Notice of Nonrenewal of Agreement	Obsolete
4-43	183	Model Public Notice of Medicare Termination Of Provider Agreement	
4-44	192	Acknowledgment of Request for Hearing	
4-45	196	Model Letter Announcing to Accrediting Hospital After a Sample Validation Survey that the Hospital Does Not Comply with All Conditions of Participation	
4-47	199	Model Letter Announcing to Accredited Hospital After a Substantial Allegation Survey that the Hospital does not Comply with All Conditions Of Participation	
4-49	194	Model Letter Announcing Compliance with all Surveyed Medicare Conditions of Participation After a Sample Validation or Substantial Allegation Survey	
4-50	197	Notice to Accredited Hospital Announcing Approval Of Plan of Correction and Completion Schedule	
4-51	198	Model Letter Announcing Compliance with All Conditions Of Participation after the Effectuation of an Acceptable Plan of Correction	
4-52	195	Model Telegram Notice Announcing to an Accredited Hospital that the Hospital Does Not Comply with all The Conditions of Participation and that there is Immediate and Serious Threat to Patient Health and Safety	
4-53	180	Notice to Accredited Psychiatric Hospital of Involuntary Termination	

LIST OF EXHIBITS - ROM

EXHIBIT ROM	SOM		Remarks:
4-67	154	Notice of Initial Approval of ESRD Facility	
4-69	155	ESRD Denial Notice	
4-71	158	Notice - Recertification of ESRD Facility	
4-72	157	Notice - Expansion and/or Additional Service (Approval, Partial Approval, or Denial of ESRD Facility)	
4-73	153	Notice of Technical Denial - Certificate of Need	
4-82	161	Notice of Approval of CAPD Services	
4-93	159	List of VA Hospitals Having Sharing Agreements With Participating ESRD Hospitals	
4-94	222	Audit Clearance Document	
4-95	Deleted	Informing New Owner that Payments are Suspended	Obsolete
4-96	218	Prerelease Notification Document	
4-97	219	Model Audit Disallowance Document	
4-98	221	Example of a Regular Disallowance Letter--Title XVIII	
4-99	Deleted	Example of a Deferral Letter	Dupl. of SOM-59
4-100	Deleted	Example of a Disallowance Letter for Amounts Previously Deferred	Dupl. of SOM-60
4-101	220	Model Audit Disallowance Letter--Title XIX	
4-151	186	Sample Memorandum Disallowing Claims for Federal Monitoring Payments (Used in Look-Behind Disapprovals)	
4-152	Deleted	Notice to Medicaid SNF of Cancellation of Eligibility to Participate	Obsolete
4-153	185	Model Telegram--Notice of Termination to a Medicaid ICF/MR Following A Look-Behind Survey; Immediate and Serious Threat to Patient Health and Safety	

LIST OF EXHIBITS - ROM

EXHIBIT ROM	---- SOM		Remarks:
4-154	Deleted	Model Letter--Approval of State's Superior Utilization Review System Waiver	Obsolete
4-155	Deleted	Model Letter--Renewal of State's Superior Review System Waiver	Obsolete
4-156	Deleted	Model Letter--Denial of State's Superior Utilization Review System Waiver	Obsolete
4-157	Deleted	Model Letter--Denial of Payments for New SNF Admissions	Obsolete
4-158	Deleted	HCFA-562, Medicare/Medicaid Complaint Form	Dupl. of SOM-75
4-159	Deleted	Model Letter--Notice to State Medicaid Agency of §1919 Options When They Apply	Obsolete
4-160	Deleted	Model Letter--Notice of Termination When §1919 Does Not Apply	Obsolete
4-161	Deleted	Model Letter--Notice of Approval of a State Medicaid Agencies Reduction Plan	Obsolete
4-162	Deleted	Model Letter--Notice of Disapproval of a State Medicaid Agencies Reduction Plan	Obsolete
4-163	Deleted	Model Letter--Notice of Approval of a State Medicaid Agencies Correction Plan	Obsolete
4-164	Delete	Model Letter--Notice of Disapproval of a State Medicaid Agencies Correction Plan	Obsolete
4-165	167	HCFA-576, HCFA-576A, Organ Procurement Organization Application and Agreement	
4-168	169	United Network for Organ Sharing	
4-169	172	Model Letter--Organ Procurement Organization Approval	
4-170	170	Model Letter A--Organ Procurement Organization Denial--Failure to Meet Requirements	
4-171	171	Model Letter B--Organ Procurement Organization Denial--Competing Applications	
4-172	100	Approval Letter for Extended Care Services (Swing-Bed) in Hospitals (50-99 Beds)	
4-173	101	Notice to Skilled Nursing Facilities that a Hospital Has Been Approved to Provide Extended Care Services (Swing-bed Services)	

LIST OF EXHIBITS - ROM

EXHIBIT ROM	SOM		Remarks:
4-174	160	Notice to ESRD Facility--Alternative Sanction For Failure to Participate with Network Goals And Objectives	
4-175	213	State Test Administration Plan	
4-176	214	Model Letter Announcing to State Survey Agency the Requirements for Administering the Long Term Care Surveyor Minimum Qualifications Test (SMQT)	
4-177	Deleted	Model Letter Informing PPS-Excluded Hospitals/Units that Self-Attestation Requirements	Obsolete
4-178	193	Model Letter Informing PPS-Excluded Hospitals And units that Reverification has been Approved	
4-179	149	Model Letter: EACH Approval Notification	
4-180	150	Model Letter: RPCH Approval Letter	
4-181	151	Model Letter: EACH Denial Letter	
4-182	152	Model Letter: RPCH Denial Letter	
4-183	Deleted	Request for Survey of 42 CFR 489.20 and 42 CFR 489.24, Essentials of Provider Agreements: Responsibilities of Medicare Participating Hospitals in Emergency Cases, HCFA-1541A	Dupl. of SOM-136
4-184	200	Model Letter Acknowledging Complaint Alleging Noncompliance with 41 CFR 489.24 And/or the Related Requirements of 41 CFR 489.20: Investigation Not Warranted	
4-185	201	Model Letter Acknowledging Complaint Alleging Noncompliance with 42 CFR 489.24 and/or The Related Requirements of 42 CFR 489.20: Investigation Not Warranted	
4-186	Deleted	Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report	Dupl. of SOM-137
4-187	202	Model Letter Requesting Physician Review of a Possible Violation of 42 CFR 489.24	
4-188	Deleted	Physician Review Outline for Emergency Care Obligations of Medicare Participating Hospitals	Dupl.. of SOM-138

LIST OF EXHIBITS - ROM

EXHIBIT ROM	SOM		Remarks:
4-189	203	Model Letter Following Investigation into Alleged Violation of 42 CFR 489.24 and/or The Related Requirements of 42 CFR 489.20: Facility in Compliance	
4-190	204	Model Letter for a Violation of 42 CFR 489.24: Preliminary Determination Letter (Immediate and Serious Threat	
4-191	205	Model Letter for a Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Preliminary Determination Letter (90-day Termination Track)	
4-192	206	Model Letter to Complainant Following Investigation of Alleged Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Complaint Not Substantiated	
4-193	207	Model Letter to Complainant Following Investigation of Alleged Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Complaint Substantiated	
4-194	208	Model Letter for Referring a Violation of 42 CFR 489.24 to the Office of Inspector General	
4-195	209	Model Letter for Referring a Violation of 42 CFR 489.24 to the Office of Civil Rights	
4-196	210	Model Letter for a Past Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: No Termination	
4-197	211	Model Letter for a Violation of 42 CFR 489.24 And/or the Related Requirements of 42 CFR 489.20: Notice of Termination	
4-198	212	Model Letter Requesting PRO Review of a Confirmed Violation of 42 CFR 489.24 for Purposes of Assessing Civil Monetary Penalties Or Excluding Physicians	
4-199	233	Fraud and Abuse--Office of Inspector General, Office of Investigations Field Offices	
4-200	225	Model Letter: Announcing Compliance with Applicable CLIA Conditions After a Sample Validation or Substantial Allegation of Noncompliance Survey	

LIST OF EXHIBITS - ROM

EXHIBIT ROM	----SOM		Remarks:
4-201	237	Model Letter: Announcing to an Accredited Laboratory After a Sample Validation Survey Of a Substantial Allegation of Noncompliance Survey that it Does Not comply with all CLIA Conditions and that there Exists Immediate Jeopardy to the Health and Safety of Individuals Or that of the General Public	
4-202	238	Model Letter: Announcing to an Accredited Laboratory after a Sample Validation Survey That the Laboratory Does Not Comply with all The CLIA Conditions - No Immediate Jeopardy	
4-203	223	Notice to Accredited Laboratory Announcing Approval of Plan of Correction and Completion Schedule for correcting Deficiencies	
4-204	224	Model Letter: Announcing to Accredited Laboratory that it is in Compliance with all Conditions after the Correction of Deficiencies	
4-205	241	Model Letter: Announcing to Accredited Laboratory AFTER a Substantial Allegation Of Noncompliance Survey that the Laboratory Does Not Comply with all CLIA Conditions (Complaint)	
4-206	226	Accredited Laboratory Allegation(s) Report, HCFA-2878A	
4-207	227	Model Letter: Announcing to the CLIA-Exempt Laboratory After a Sample Validation or Substantial Allegation of Noncompliance Survey That it does not Comply with Application Program Activities	
4-208	231	Model Letter: Announcing to the CLIA-Exempt Laboratory, after a Sample Validation or Substantial Allegation of Noncompliance Survey that it does not Comply with Applicable Program Requirements (No Immediate Jeopardy)	
4-209	242	Request for Validation of Accreditation Survey For Laboratories, HCFA-2802A	
4-210	228	Model Letter: Announcing to the State Laboratory Program, After a Sample Validation or Substantial Allegation of Noncompliance Survey, that a CLIA-exempt Laboratory does not Comply with Applicable Program Requirements	

LIST OF EXHIBITS - ROM

EXHIBIT ROM	---- SOM		Remarks:
4-211	232	Model Letter: Announcing to the State Laboratory Program, After a Sample Validation or Substantial Allegation of Noncompliance Survey, that a CLIA-exempt Laboratory does not Comply with Applicable Program Requirements (No Immediate Jeopardy)	
4-212	229	Model Letter: Announcing to the CLIA-Exempt Laboratory, that HCFA will Seek a Temporary Injunction or Restraining Order	
4-213	230	Model Letter: Announcing to the State Laboratory Licensure Program that HCFA will Seek a Temporary Injunction or Restraining Order to Enjoin Continued Operation	
4-214	243	Model Letter: Announcing to a CLIA Exempt Laboratory That it is in Compliance with the CLIA Conditions after a Sample Validation or Substantial Allegation of Noncompliance Survey	
4-215	244	Model Letter: Announcing to the State Laboratory Program, that a CLIA-Exempt Laboratory is in Compliance with the CLIA Conditions after a Sample Validation or Substantial Allegation of Noncompliance Survey	
4-216	Deleted	CLIA Adverse Action Extract, HCFA-462A/B	Obsolete
4-217	Deleted	Notice of Denial of a Laboratory's Request for A CLIA Certificate, or a CLIA Certificate of Accreditation	Obsolete
4-218	246	Model Letter: Regional Office Notifying a State-Operated Laboratory of Cited Deficiencies and Requesting a Plan of Correction	
4-219	247	Notice of (Limitation or) Revocation of a Laboratory's CLIA Certificate - No Immediate Jeopardy	
4-220	235	Notice of Suspension or Limitation of the CLIA Certificate - Immediate Jeopardy	
4-221	248	Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate; Opportunity For a Hearing - No Immediate Jeopardy	
4-222	234	CLIA Notice of Noncompliance and Proposed Alternative Sanction(s) - No Immediate Jeopardy	

LIST OF EXHIBITS - ROM

EXHIBIT ROM	SOM		Remarks:
4-223	236	Notice of Imposition of Sanction(s); Acknowledgment of Information Received	
4-224	249	Model Letter: Send to the Laboratory in Conjunction with the Notice of Sanction, In order to Officially Inform the Laboratory That the Responsibility Lies with the Laboratory to Achieve Compliance, Even if They Have Successfully Completed the Directed Plan of Correction	
4-225	250	Notice of the Reissuance of a CLIA Certificate In Order to Keep a Laboratory Operational if it Is Due to Expire Prior to the Administrative Hearing	
4-226	251	Model Letter: Offering the Opportunity for a Reconsideration if the Addition of Specialties Or Subspecialties by a Laboratory is Denied By HCFA	
4-227	Deleted	Model Letter: Laboratory Informs RO of Plans to Cease Operation	Obsolete
4-228	Deleted	Model Letter: Laboratory Informs RO that It Has Ceased Operation	Obsolete
4-229	240	Notice of Proposed Limitation of the CLIA Certificate and Suspension of Medicare Payments When a Laboratory Has Failed to Participate Successfully in a Proficiency Testing Program	
4-330	176	Model Letter: Organ Procurement Organization Corrective Action Notice	
4-331	173	Model Letter: Organ Procurement Organization Notice of Termination	
4-332	174	Model Letter: Organ Procurement Organization Notice to Public and State Medicaid/Medicare Agencies	
4-333	175	Model Letter: Organ Procurement Organization Notice to Bordering OPOs	
4-334	168	Organ Procurement Organization Report	

CHAPTER 1

PROGRAM BACKGROUND AND RESPONSIBILITIES

	Section
Medicare and Medicaid - Background	1000
Basis for State Agency (SA) Activities Under Title XVIII and Title XIX of the Act	1002
Title XVIII Agreements with States	1004
HCFA's Role	1006
Adjudication Authority	1008
Certification Related Functions of SA	1010
Explanation of Certification and Survey	1012
Relationship of Survey Date to Date of Initial Medicare Approval	1014
Approval and Correction of Deficiencies	1016
Exceptions to SA Certification	1018
Effect of Accreditation, Licensure, and Other Approval Programs on Medicare Standards	1020

Background

1000. MEDICARE AND MEDICAID - BACKGROUND

The Social Security Act (the Act) mandates the establishment of minimum health and safety standards which must be met by providers and suppliers participating in the Medicare and Medicaid programs. The Secretary of the Department of Health and Human Services (DHHS) has designated the Health Care Financing Administration (HCFA) to administer the standards compliance aspects of these programs.

A. Medicare Provisions.--Medicare is a Federal insurance program providing a wide range of benefits for specific periods of time through providers and suppliers participating in the program. Providers, in Medicare terminology, are patient care institutions such as hospitals, hospices, nursing homes, and home health agencies. Suppliers are agencies for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics, and physical therapist (PT) offices. The Act designates those providers and suppliers which are subject to Federal health care quality standards. Benefits are payable for most people over age 65, Social Security beneficiaries under 65 entitled to disability benefits, and individuals needing renal dialysis or renal transplantation. Payment for services is made by the Federal Government through designated fiscal intermediaries (FIs) and carriers to the providers and suppliers. Section 1802 of the Act provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate in Medicare if that institution, agency or person provides such services.

B. Medicaid Provisions.--Medicaid is a State program that provides medical services to clients of the State public assistance program and, at the State's option, other needy individuals, as well as augments hospital and nursing facility (NF) services that are mandated under Medicaid. States may decide on the amount, duration, and scope of additional services, except that care in institutions primarily for the care and treatment of mental disease may not be included for persons over age 21 and under age 65. When services are furnished through institutions which must be certified for Medicare, the institutional standards must be met for Medicaid as well. In general, the only types of institutions participating solely in Medicaid are NFs and intermediate care facilities for the mentally retarded (ICFs/MR). Medicaid requires NFs to meet virtually the same requirements that skilled nursing facilities (SNFs) participating in Medicare must meet. ICFs/MR must comply with special Medicaid standards. 42 CFR Part 431.51 provides Medicaid recipients free choice of providers.

1002. BASIS FOR STATE AGENCY (SA) ACTIVITIES UNDER TITLE XVIII AND TITLE XIX OF THE ACT

Section 1864(a) of the Act directs the Secretary to use the help of State health agencies or other appropriate agencies when determining whether health care entities meet Federal standards. This helping function is termed "provider certification."

Section 1902(a)(9)(A) of the Act requires that a State use this same agency to set and maintain additional standards for the State Medicaid program. Section 1902(a)(33)(B) requires that the State use the agency utilized for Medicare or, if such agency is not the State agency responsible for licensing health institutions, the State use the agency responsible for such licensing to determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary.

The complete Federal requirements are published in the Federal Register, and they are further explained in this manual. (See title 42, Code of Federal Regulations (CFR), Chapter IV.)

1004. TITLE XVIII AGREEMENTS WITH STATES

Agreements between the Secretary and the various States, territories, and the District of Columbia stipulate that SAs designated by the Governors are responsible for the performance of the certification functions created by §1864 of the Act, that the designated agencies will keep necessary and appropriate records to be furnished as required by delegates of the Secretary, and that they will employ management methods, personnel procedures, equal opportunity policies, and merit systems procedures in accordance with agreed upon or established practices. The Secretary agrees to provide funds for the reasonable and necessary costs to the States of performing the functions authorized by the agreements. The lifetime of the agreements is unlimited, but an agreement may be terminated under specific conditions, by action of either of the parties. The Governors have the prerogative to propose modification of the agreements to allow for variations in organizational location of responsibilities within the State for Federal programs and for State health facilities licensure. The SA's responsibility for evaluation and certification may not be redelegated. However, by arrangements which meet the express approval of the Secretary, subsidiary functions such as the performance of surveys and investigations may be assigned to other State government units or other agencies. When the reorganization of a State government affects the responsibilities of the designated agency, or in any way affects the arrangements previously recognized by the §1864 agreement, modification or renegotiation of the agreement may be necessary.

The Secretary may, under §1874 of the Act, contract with State or other agencies for services included in sections of the Act other than §1864 when the Secretary finds that such contracts would be in the interest of effective program operations.

Chapter 4 of this manual contains information on the administration of these agreements.

1006. HCFA'S ROLE

The primary mission of HCFA is to administer the Medicare program and certain related provisions of the Act in a manner which:

- Promotes the timely and economic delivery of appropriate quality of care to eligible beneficiaries;
- Promotes beneficiary awareness of the services for which they are eligible; and
- Promotes efficiency and quality within the total health care delivery system.

Overall policy-making responsibility is centralized in HCFA's Baltimore headquarters, where all aspects of the Medicare program and oversight of the State Medicaid programs are coordinated. HCFA is responsible for:

- Monitoring, surveillance, and overall administrative control of the certification process including its financial aspects;
- Establishing operational policy for the certification process; and
- Conveying operational instructions and official interpretations of policy to the SAs and the HCFA regional offices (ROs).

The HCFA ROs are responsible for assuring that health care providers and suppliers participating in the Medicare and Medicaid programs meet applicable Federal requirements. This is accomplished through various activities. The RO:

o Makes final determinations of provider and supplier eligibility for participation in the Medicare program. Also assembles information on all determinants of eligibility; approves, denies, or terminates provider agreements and supplier participation; and arranges for FI tie-in with new providers;

o Evaluates the performance of SAs in interpreting and applying health and safety standards, their assessments of providers and suppliers for compliance with standards, and their use of appropriate administrative procedures;

o Provides liaison, direction, and technical assistance to SAs in the day-to-day management of the certification process;

o Interprets HCFA guidelines, policies, and procedures applicable to certification activities;

o Analyzes and negotiates State Medicare certification budgets; analyzes State spending patterns to assure that funds are economically and appropriately utilized; and allocates SA funds for conducting certification activities;

o Conducts surveillance and assessments of SA operations and assists SAs in developing the capability to provide direct assistance to providers and suppliers, reviews SA certification actions, and provides feedback to States;

o Prepares data based on SA survey findings for input into HCFA's Online Data Input and Edit (ODIE) system (ODIE is a subsystem of the Online Survey Certification and Reporting (OSCAR) system, which is a database and retrieval program); analyzes OSCAR data, and provides feedback to SAs on certification information tracked by the system; and

o Conducts Federal surveys of providers and suppliers to ensure that standards and procedures are being applied in a uniform and consistent manner.

1008. ADJUDICATION AUTHORITY

A. Medicare Approval.--The authority of the Secretary of DHHS to approve, disapprove, or terminate the Medicare participation of certified providers and suppliers is delegated to the ten HCFA ROs.

EXCEPTION: If termination is on grounds of fraud, program abuse, or noncompliance with peer review requirements, the authority to terminate or to establish eligibility for reinstatement reposes with the Office of Inspector General (OIG), DHHS.

B. Medicaid Approval.--With the exception of State-operated Medicaid-only NFs, Medicaid law requires that the same SA which makes the certifications for Medicare provider and supplier eligibility also make the determinations for Medicaid eligibility. The law also requires that there be a designated State Medicaid Agency (SMA) responsible for the overall management of the Medicaid program. (See 42 CFR Part 431.610). For State-operated Medicaid-only NFs, §1919 of the Act specifies that the Secretary will have adjudication authority. There is in each State an

SMA which is ultimately responsible to HCFA for the Medicaid program administration. Each SMA must enter into an interagency agreement with the certifying SA, establishing the adjudicative function of the certifying SA and providing for the application of Federal certification standards and procedures. The SMA must accept the SA's certification decisions as final, but exercises its own determination whether to enter into agreements with the approved providers. (See subsection E.)

C. Compliance With Title VI of the Civil Rights Act of 1964.--Providers are direct recipients of Federal funds and are thus subject to title VI of the Civil Rights Act of 1964. The U.S. Office for Civil Rights (OCR) has the authority to determine whether Medicare providers comply with this non-discrimination statute, and the Conditions of Participation (CoPs) make OCR approval a precondition for Medicare approval by HCFA. Before OCR will issue its approval, it also determines compliance with §504 of the Rehabilitation Act of 1973 as amended by the Rehabilitation Act Amendments of 1974 (which includes a cross reference to the Uniformed Federal Accessibility Standards concerning architectural barriers to the handicapped), the Age Discrimination Act of 1975, and with title IX of the Education Amendments of 1972. (See Exhibit 2) (See 45 C.F. Part 84.)

Regarding Medicaid-only providers, the States themselves are considered the direct recipients of the Federal funds and may be considered to have a direct obligation to assure OCR of their compliance by assuring that funds go to providers who are in compliance. As with Medicare, determinations of civil rights compliance of providers are under the authority of OCR and are preconditions to approving the provider's participation in the Medicaid program. .

D. Waivers of Standards.--For a few of the standards, the statute or regulations allow for waivers in the presence of verified temporary shortages of health personnel or in the presence of equivalent alternative patient safeguards. Medicare waiver authority is redelegated to the ROs. Waivers for NFs to provide licensed personnel on a 24 hour basis repose with the States, as does waivers for ICFs/MR. Life safety code (LSC) waivers for NFs are the responsibility of the RO.

E. Look-Behind Authority.--The Secretary has authority under §§1902(a)(33), 1919(g)(3), and 1910(b)(1) of the Act to cancel approval of all Medicaid facilities, including NFs and ICFs/MR, that do not meet Federal health or safety requirements. Such a determination is in lieu of or overrides one by the State and is binding on the SMA. Section 1902(a)(33) gives HCFA the authority to question State determinations regarding Medicaid facilities' compliance with Federal requirements and directs HCFA to make independent and binding determinations concerning the extent to which individual institutions and agencies meet requirements for participation.

Section 1919(g)(3)(A) states that if the State determines that an individual NF meets Federal requirements, but HCFA determines that the facility does not meet such requirements, HCFA's determination as to the facility's noncompliance is binding and supersedes that of the State.

Section 1910(b)(1) (new look-behind) gives HCFA similar authority to terminate the Medicaid approval of ICFs/MR. HCFA's decision to cancel the approval or terminate an ICF/MR can be made as the result of complaint or Federal validation surveys or HCFA's review of SA survey findings.

HCFA also may, under 42 CFR Part 442.30, invalidate a Medicaid provider agreement after determining that the agreement does not constitute valid evidence of the provider's compliance with

the Federal regulatory requirements. In the latter situation, the effect is to deny and recoup all Federal matching funds in the Medicaid payments to the facility that were made under the improper agreement. The authority to investigate and either cancel approval or invalidate improper agreements, called "old" look-behind authority, is redelegated to an office in each HCFA RO.

F. Authorization of Certification Expenditures.--Authority to approve Medicare certification budgets and expenditures is redelegated to the regional administrators (RAs). Authority to approve or disapprove Federal financial participation (FFP) in Medicaid certification expenses is redelegated to the RAs subject to ratification by the Medicaid Bureau, HCFA.

G. Appeals.--All of the appeal authorities do not repose with HCFA. All HCFA RO notices of adverse determinations include instructions on the proper filing and addressing of the appropriate appeal. .

H. Compliance With Civilian Health and Medical Program of Uniformed Services (CHAMPUS) and/or Civilian Health and Medical Program of Veterans Administration (CHAMPVA) Requirements.--For the provision of inpatient hospital services pursuant to admissions occurring on or after January 1, 1987, providers are required to participate in the CHAMPUS/CHAMPVA programs. As mandated by §1866(a)(1)(J) of the Act, providers are subject to implementing regulations governing CHAMPUS/CHAMPVA programs benefits under title 10, §1079 or §1086 of chapter 55 - Medical and Dental Care of the CHAMPUS; and title 38, §613 of chapter 17 - Hospital, Nursing Home, Domiciliary, and Medical Care of the CHAMPVA. Such regulations are found in 32 CFR Part 199 for CHAMPUS and 38 CFR 17.54 for CHAMPVA. Inpatient hospital care to CHAMPUS and/or CHAMPVA beneficiaries is subject to the specific eligibility and medical service limitations set forth in the regulations. Hospitals are to accept CHAMPUS and/or CHAMPVA reimbursement for such services as payment in full. The Secretary has authority under §1866(b)(2) of the Act to terminate provider agreements for noncompliance. (See 42 CFR Part 489.25.)

NOTE: This requirement relates to individuals whose inpatient care is covered under the CHAMPUS and CHAMPVA programs, not to Medicare beneficiaries who, though eligible for these programs, are using Medicare as the primary payor for their services. (See Hospital Manual §2603.E.5.)

I. Compliance With VA Program Requirements.--For the provision of inpatient hospital services pursuant to admissions occurring on or after July 1, 1987, providers must agree to be a participating provider of care to Veterans Administration patients. As mandated by §1866(a)(1)(L) of the Act, providers are subject to implementing regulations governing VA program benefits under title 38, §603. The provision of inpatient hospital care to veterans is subject to the specific limitations set forth in 38 CFR 17.50b. Hospitals must accept VA reimbursement for such services as payment in full. The Secretary has authority under §1866(b)(2) of the Act to terminate provider agreements for noncompliance. (See 42 CFR Part 489.26.)

NOTE: This requirement relates to veterans whose inpatient care is covered under the VA program, not to Medicare beneficiaries who are also eligible for VA coverage. (See Hospital Manual §260.3.B.)

1010. CERTIFICATION RELATED FUNCTIONS OF SA

The functions which the SAs perform under the agreements in §1864 of the Act, are referred to collectively as the certification process. This includes, but are not limited to:

A. Identifying Potential Participants.--The law guarantees to Medicare beneficiaries that payment will be made for health services furnished in or by entities which meet stipulated requirements of the Act. Identification includes those laboratories seeking to participate in the CLIA program.

B. Conducting Investigations and Fact-Finding Surveys.--Verifying how well the health care entities comply with the CoPs/requirements.

C. Certifying and Recertifying.--Certifications are periodically sent to the appropriate Federal or State agencies regarding whether entities, including CLIA laboratories, are qualified to participate in the programs.

D. Explaining Requirements.--Advising providers and potential providers in regard to applicable Federal regulations to enable them to qualify for participation in the programs and to maintain standards of health care consistent with the CoPs/requirements.

Also, as mandated by §§1819(g)(1)(B) and 1919(g)(1)(B) of the Act, States must conduct periodic educational programs for the staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies.

E. Operating Toll-Free Home Health Hotline.--Maintain a toll-free telephone hotline to collect, maintain, and continually update information on Medicare-certified HHAs. The hotline is also used to receive complaints and answer questions about HHAs in the State or locality. (See §1864(b) of the Act.)

The SA is also authorized to perform numerous other functions under a blanket clause of its SA agreement, by special agreement, or by statute. These include:

F. Identifying Prospective Payment System (PPS) Excluded Institutions. Certification information helps in identifying institutions or components of institutions that meet special requirements qualifying them to be excluded from the Medicare PPS.

G. Participating on Validation Surveys of Accredited Entities.--These surveys are intended to furnish DHHS and Congress a monitoring of the validity of "deeming" that accredited entities meet the CoPs.

H. Proficiency Testing.--Monitor programs of proficiency testing in laboratories and contribute laboratory compliance findings to use in the CLIA Laboratory Certification Program.

I. Direct Data Entry.--Enter data from surveys, follow-up visits, and complaint investigations into the OSCAR/ODIE system, the national mainframe computer system that is used for maintaining and retrieving certification data. Update information about providers, suppliers, and CLIA laboratories in the system when indicated.

J. Nurse Aide Training.--Specify and review Nurse Aide Training and Competency Evaluation Programs (NATCEPs) and/or Nurse Aide Competency Evaluation Programs (NACEPs). (See §§1819(e)(1) and 1919(e)(1) of the Act.)

K. Nurse Aide Registry (NAR).--Establish and maintain a registry for all individuals who have satisfactorily completed NATCEP or a NACEP. (See Chapter 4, §4145 of this manual and §§1819(e)(2) and 1919(e)(2) of the Act.)

L. Resident Assessment Instrument (RAI).--Specify a RAI for use in the LTC facilities participating in Medicare and/or Medicaid. (See Chapter 4, §4145.4 of this manual.)

M. Records and Reports.--Maintain pertinent survey, certification, statistical, or other records for a period of at least 4 years and make reports in the form and content as the Secretary may require.

1012. EXPLANATION OF CERTIFICATION AND SURVEY

A. Meaning of Certification.--Certification is when the SA officially certifies its findings whether health care entities meet the Act's provider or supplier definitions, and whether the entities comply with standards required by Federal regulations. SAs do not have Medicare determination-making functions or authorities. Their certifications are the crucial evidence relied upon by the ROs in approving health care entities to participate in Medicare and CLIA. Recertifications are performed periodically by the SAs.

Regardless of whether the finding is for Medicare, Medicaid, or CLIA purposes, the SA surveys an institution in exactly the same way to ascertain whether it meets the Federal health and safety requirements for participation. However, when the institution participates only in Medicaid, the SA finding constitutes a binding adjudicative determination. When the institution participates in both Medicare and Medicaid, the RO determination is binding for both programs regardless of whose decision prevails in the case of SNFs and NFs.

Surveys are necessary for the SA to be able to certify. The law provides Federal funding for these surveys. SAs survey many institutions simultaneously for Medicare, Medicaid, and State licensure, and sometimes for other inspection programs, so the costs are equitably allocated between the sharing programs.

Part of a survey may concern a provider's efforts to prevent environmental hazards due to contagion, fire, contamination, or structural design and maintenance problems. However, a survey is not a mere building inspection nor a "white glove inspection" which, on no more than an annual basis, would be pointless. Its more realistic focus is ascertaining that the responsible provider officials and key personnel are effectively doing all they must do to protect health and safety.

Many aspects of the survey are accomplished by scrutinizing the provider's records to show that professional staff members have been properly noting and evaluating the progress of patients' care or managing provider operations with continuing vigilance. Surveys of SNFs, NFs, HHAs, and ICFs/MR are conducted in accordance with outcome oriented survey protocols, which were designed to concentrate on patient/resident/client outcomes of care in determining the provider's

compliance with the Federal requirements rather than focusing on "process oriented" requirements. The certification is not questioned merely on grounds that the institution has expanded, moved, or slightly modified the scope of its services, unless it might have changed the quality of the services provided or type of certification in doing so. (Refer to 42 CFR Part 488.26 and 488.330.)

1014. RELATIONSHIP OF SURVEY DATE TO DATE OF INITIAL MEDICARE APPROVAL

A provider or supplier cannot begin to have its services covered and reimbursed by Medicare until the date on which it is found, via the certification process, to be in compliance with all applicable CoPs or in substantial compliance with the requirements for SNFs and NFs, or Conditions for Coverage if it is a supplier (42 CFR Part 489.13). A laboratory with a CLIA registration certificate is an exception to this rule. In most cases, it usually is impossible to schedule and complete a survey, i.e., ascertain actual compliance with all applicable requirements, on the date a new institution opens its doors. The institution generally must operate for a short initial period without Medicare payment for its services.

1016. APPROVAL AND CORRECTION OF DEFICIENCIES

The Medicare CoPs, Requirements for SNFs and NFs, and Conditions for Coverage are sets of requirements for acceptable quality in the operation of health care entities. There is a set of Conditions, or Requirements for SNFs and NFs, for each type of provider or supplier subject to SA certification. In addition to each Condition, or Requirement for SNFs and NFs, is a group of related quality standards, with the Condition or Requirement expressed in a summary lead sentence or paragraph characterizing the quality or result of operations to which all the subsidiary standards are directed. The SA ascertains, by a survey conducted by qualified health professionals, whether and how each standard is met. While an institution may fail to comply with one or more of the subsidiary standards during any given survey, it cannot participate in Medicare unless it meets each and every Condition or attains substantial compliance with requirement for SNFs and NFs.

(Many Condition or Requirement summaries are identical to statements of the statute.) The essence of what the SA certifies to HCFA is a finding of whether each institution meets each of the Conditions or substantially meets each Requirement for SNFs and NFs applicable to it.

The SA prepares its certification for the RO, send the institution a statement of deficiencies, Form HCFA-2567. The institution is given 10 days in which to respond with a Plan of Correction (PoC) for each cited deficiency, and enters this response on the form containing the statement of deficiencies. (This form is available for public inspection at the SA office and the nearest RO.)

If the institution has not come into compliance with all conditions or requirements for SNFs and NFs within the time period accepted as reasonable, the SA certifies noncompliance notwithstanding a PoC.

The SA's finding constitutes a final determination (except in the case of a State-operated Medicaid-only NF or a NF subject to a validation survey or a review by HCFA when HCFA's decision is binding), when a Medicaid-only facility is noncompliant. The SMA must undertake either an action to terminate the noncomplying facility's Medicaid participation or, if a NF, apply one or more of the remedies specified in §1919(h) of the Act, or may do both.

1018. EXCEPTIONS TO SA CERTIFICATION

A. Federal and Indian Health Institutions.--Because of questions of intergovernmental jurisdiction, the survey and certification of a hospital or SNF that is either owned or operated by the Indian Health Service (IHS) (and therefore considered to be a Federal provider of services) is handled by the RO. The SA is responsible, however, for determining whether the facility meets Medicaid certification requirements. The SA may accept Medicare certification as sufficient evidence of meeting Medicaid requirements, or the SA may conduct a survey.

Indian health tribal facilities are not considered to be Federal providers and are surveyed by the SA.

B. Christian Science Sanatoria.--Section 1861(e) of the Act includes in the definition of "hospital" a Christian Science Sanatorium which is operated or listed and certified by the First Church of Christ, Scientist, in Boston, Massachusetts, with respect to certain items and hospital services furnished to inpatients. Section 1861(y) includes sanatoria with respect to items and services furnished to inpatients in a long term care setting. All approvals are handled by the Boston RO. No SA certifications are necessary. The State may also include these services under the State plan for Medicaid.

C. Accredited Hospitals.--Sections 1861(e) and 1865(a) of the Act allow institutions accredited as hospitals by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or by the American Osteopathic Association (AOA) to be deemed to meet the CoPs, with the exception of the following:

- o The utilization review (UR) condition;
- o A standard promulgated by the Secretary which is a higher-than-accreditation requirement;
- o The two special Conditions for psychiatric hospitals; and
- o Any higher-than-national standards approved by the Secretary and applied in a particular State.

D. Accredited HHAs.--HHAs accredited by the Community Health Accreditation Program (CHAP) as of August 28, 1992, and JCAHO as of September 28, 1993, are deemed to meet the CoPs.

E. Accredited ASCs.--ASC's accredited by the Accreditation for Ambulatory Health Care (AAAHC) and the JCAHO as of December 19, 1996, are deemed to meet the CoPs.

F. Accredited CLIA Laboratories.--Because each accrediting organization that has received deeming authority (under CLIA) is approved for specific laboratory specialities/subspecialities consult the RO for specific guidance. Refer to Chapter six for additional information on accrediting organizations. Each of the following organizations are approved for distinct specialities/subspecialties:

- o American Association of Blood Banks;
- o American Osteopathy Association;

- o American Society of Histocompatibility and Immunogenetics;
- o Joint Commission on Accreditation of Healthcare Organizations;
- o College of American Pathologists; and,
- o Commission on Office Laboratory Accreditation

G. Exemption of Laboratories Licensed by States.--CLIA will exempt laboratories in States that have been determined to have laws and regulations in effect that are equal to or more stringent than CLIA requirements. Exempt laboratories must hold a valid State license within the exempt State. Oregon and Washington State have been granted complete exemption. New York State has been granted a partial exemption. Refer to Chapter 6 for additional information on CLIA exempt laboratories organizations.

H. Eligibility for Medicaid Facilities.--Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type. See 42 CFR Part 488.6.

1020. EFFECT OF ACCREDITATION, LICENSURE, AND OTHER APPROVAL PROGRAMS ON MEDICARE STANDARDS

Certification requirements, State licensure codes for health facilities, programs for professional licensure and accreditation, and medical assistance standards are all related. Coordinate the SA certification activities with the other programs; thus, certification builds upon State and national accreditation programs. Interchange of information between the certifying agency, accrediting organizations, State licensure programs, and State medical assistance programs about program standards and institutions that participate in these programs is important. Development of these relationships is encouraged.